

108TH CONGRESS
2D SESSION

S. 2464

To amend the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs through the Internet.

IN THE SENATE OF THE UNITED STATES

MAY 20, 2004

Mr. COLEMAN (for himself, and Mrs. FEINSTEIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the sale of prescription drugs through the Internet.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Internet Pharmacy
5 Consumer Protection Act” or the “Ryan Haight Act”.

6 **SEC. 2. INTERNET SALES OF PRESCRIPTION DRUGS.**

7 (a) IN GENERAL.—Chapter 5 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
9 ed by inserting after section 503A the following:

1 **“SEC. 503B. INTERNET SALES OF PRESCRIPTION DRUGS.**

2 “(a) REQUIREMENTS REGARDING INFORMATION ON
3 INTERNET SITE.—

4 “(1) IN GENERAL.—A person may not dispense
5 a prescription drug pursuant to a sale of the drug
6 by such person if—

7 “(A) the purchaser of the drug submitted
8 the purchase order for the drug, or conducted
9 any other part of the sales transaction for the
10 drug, through an Internet site; and

11 “(B) such site, or any other Internet site
12 used by such person for purposes of sales of a
13 prescription drug, fails to meet each of the re-
14 quirements specified in paragraph (2) (other
15 than a site or pages on a site that are not in-
16 tended to be accessed by purchasers or prospec-
17 tive purchasers or that provide an Internet in-
18 formation location tool within the meaning of
19 section 231(e)(5) of the Communications Act of
20 1934 (47 U.S.C. 231(e)(5)).

21 “(2) REQUIREMENTS.—With respect to an
22 Internet site, the requirements referred to in sub-
23 paragraph (B) of paragraph (1) for a person to
24 whom such paragraph applies are as follows:

1 “(A) Each page of the site shall include ei-
2 ther the following information or a link to a
3 page that provides the following information:

4 “(i) The name of such person; the ad-
5 dress of the principal place of business of
6 the person with respect to sales of pre-
7 scription drugs through the Internet; and
8 the telephone number for such place of
9 business.

10 “(ii) Each State in which the person
11 is authorized by law to dispense prescrip-
12 tion drugs.

13 “(iii) The name of each individual
14 who serves as a pharmacist for purposes of
15 the site; and each State in which the indi-
16 vidual is authorized by law to dispense pre-
17 scription drugs.

18 “(iv) If the person provides for med-
19 ical consultations through the site for pur-
20 poses of providing prescriptions, the name
21 of each individual who provides such con-
22 sultations; each State in which the indi-
23 vidual is licensed or otherwise authorized
24 by law to provide such consultations or
25 practice medicine; and the type or types of

1 health professions for which the individual
 2 holds such licenses or other authorizations.

3 “(B) A link to which paragraph (1) applies
 4 shall be displayed in a clear and prominent
 5 place and manner, and shall include in the cap-
 6 tion for the link the words ‘licensing and con-
 7 tact information’.

8 “(b) INTERNET SALES WITHOUT APPROPRIATE
 9 MEDICAL RELATIONSHIPS.—

10 “(1) IN GENERAL.—A person may not dispense
 11 a prescription drug, or sell such a drug, if—

12 “(A) for purposes of such dispensing or
 13 sale, the purchaser communicated with the per-
 14 son through the Internet;

15 “(B) the patient for whom the drug was
 16 dispensed or purchased did not, when such
 17 communications began, have a prescription for
 18 the drug that is valid in the United States;

19 “(C) pursuant to such communications, the
 20 person provided for the involvement of a practi-
 21 tioner, or an individual represented by the per-
 22 son as a practitioner, and the practitioner or
 23 such individual issued a prescription for the
 24 drug that was purchased;

1 “(D) the person knew, or had reason to
 2 know, that the practitioner or the individual re-
 3 ferred to in subparagraph (C) did not, when
 4 issuing the prescription, have a qualifying med-
 5 ical relationship with the patient; and

6 “(E) the person received payment for the
 7 dispensing or sale of the drug.

8 For purposes of subparagraph (E), payment is re-
 9 ceived if money or other valuable consideration is re-
 10 ceived.

11 “(2) QUALIFYING MEDICAL RELATIONSHIP.—

12 “(A) IN GENERAL.—With respect to
 13 issuing a prescription for a drug for a patient,
 14 a practitioner has a qualifying medical relation-
 15 ship with the patient for purposes of this sec-
 16 tion if at least 1 in-person medical evaluation of
 17 the patient has been conducted by the practi-
 18 tioner.

19 “(B) IN-PERSON MEDICAL EVALUATION.—

20 A medical evaluation by a practitioner is an in-
 21 person medical evaluation for purposes of this
 22 section if the practitioner is in the physical
 23 presence of the patient as part of conducting
 24 the evaluation, without regard to whether por-

tions of the evaluation are conducted by other health professionals.

“(3) RULES OF CONSTRUCTION.—

“(A) INDIVIDUALS REPRESENTED AS PRACTITIONERS.—A person who is not a practitioner (as defined in subsection (e)(1)) lacks legal capacity under this section to have a qualifying medical relationship with any patient.

“(B) APPLICABILITY OF REQUIREMENTS.—Paragraph (2) may not be construed as having any applicability beyond this section, and does not affect any State law, or interpretation of State law, concerning the practice of medicine.

“(C) STANDARD PRACTICE OF PHARMACY.—Paragraph (1) may not be construed as prohibiting any conduct that is a standard practice in the practice of pharmacy.

“(c) ACTIONS BY STATES.—

“(1) IN GENERAL.—Whenever an attorney general of any State has reason to believe that the interests of the residents of that State have been or are being threatened or adversely affected because any person has engaged or is engaging in a pattern or practice that violates section 301(l), the State

1 may bring a civil action on behalf of its residents in
2 an appropriate district court of the United States to
3 enjoin such practice, to enforce compliance with such
4 section (including a nationwide injunction), to obtain
5 damages, restitution, or other compensation on behalf
6 of residents of such State, to obtain reasonable attor-
7 neys' fees and costs if the State prevails in the civil
8 action, or to obtain such further and other relief as
9 the court may deem appropriate.

10 “(2) NOTICE.—The State shall serve prior writ-
11 ten notice of any civil action under paragraph (1) or
12 (5)(B) upon the Secretary and provide the Secretary
13 with a copy of its complaint, except that if it is not
14 feasible for the State to provide such prior notice,
15 the State shall serve such notice immediately upon
16 instituting such action. Upon receiving a notice re-
17 specting a civil action, the Secretary shall have the
18 right—

19 “(A) to intervene in such action;

20 “(B) upon so intervening, to be heard on
21 all matters arising therein; and

22 “(C) to file petitions for appeal.

23 “(3) CONSTRUCTION.—For purposes of bring-
24 ing any civil action under paragraph (1), nothing in
25 this chapter shall prevent an attorney general of a

1 State from exercising the powers conferred on the
 2 attorney general by the laws of such State to con-
 3 duct investigations or to administer oaths or affir-
 4 mations or to compel the attendance of witnesses or
 5 the production of documentary and other evidence.

6 “(4) VENUE; SERVICE OF PROCESS.—

7 “(A) VENUE.—Any civil action brought
 8 under paragraph (1) in a district court of the
 9 United States may be brought in the district in
 10 which the defendant is found, is an inhabitant,
 11 or transacts business or wherever venue is prop-
 12 er under section 1391 of title 28, United States
 13 Code.

14 “(B) SERVICE OF PROCESS.—Process in
 15 such an action may be served in any district in
 16 which the defendant is an inhabitant or in
 17 which the defendant may be found.

18 “(5) ACTIONS BY OTHER STATE OFFICIALS.—

19 “(A) EFFECT OF SECTION.—Nothing con-
 20 tained in this section shall prohibit an author-
 21 ized State official from proceeding in State
 22 court on the basis of an alleged violation of any
 23 civil or criminal statute of such State.

24 “(B) ADDITIONAL ACTION.—In addition to
 25 actions brought by an attorney general of a

1 State under paragraph (1), such an action may
 2 be brought by officers of such State who are
 3 authorized by the State to bring actions in such
 4 State on behalf of its residents.

5 “(d) INTERACTIVE COMPUTER SERVICE; ADVER-
 6 TISING.—No provider of an interactive computer service,
 7 as defined in section 230(f)(2) of the Communications Act
 8 of 1934 (47 U.S.C. 230(f)(2)), or of advertising services
 9 shall be liable under this section for dispensing or selling
 10 prescription drugs in violation of this section on account
 11 of another person’s selling or dispensing such drugs, pro-
 12 vided that the provider of the interactive computer service
 13 or of advertising services does not own or exercise cor-
 14 porate control over such person.

15 “(e) DEFINITIONS.—For purposes of this section:

16 “(1) PRACTITIONER.—The term ‘practitioner’
 17 means a practitioner referred to in section 503(b)(1)
 18 with respect to issuing a written or oral prescription.

19 “(2) PRESCRIPTION DRUG.—The term ‘pre-
 20 scription drug’ means a drug that is subject to sec-
 21 tion 503(b)(1).

22 “(3) QUALIFYING MEDICAL RELATIONSHIP.—
 23 The term ‘qualifying medical relationship’, with re-
 24 spect to a practitioner and a patient, has the mean-
 25 ing indicated for such term in subsection (b).”.

1 (b) INCLUSION AS PROHIBITED ACT.—Section 301 of
 2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 3 331) is amended by inserting after paragraph (k) the fol-
 4 lowing:

5 “(l) The dispensing or selling of a prescription drug
 6 in violation of section 503B.”.

7 (c) INTERNET SALES OF PRESCRIPTION DRUGS;
 8 CONSIDERATION BY SECRETARY OF PRACTICES AND PRO-
 9 CEDURES FOR CERTIFICATION OF LEGITIMATE BUSI-
 10 NESSES.—In carrying out section 503B of the Federal
 11 Food, Drug, and Cosmetic Act (as added by subsection
 12 (a)), the Secretary of Health and Human Services shall
 13 take into consideration the practices and procedures of
 14 public or private entities that certify that businesses sell-
 15 ing prescription drugs through Internet sites are legiti-
 16 mate businesses, including practices and procedures re-
 17 garding disclosure formats and verification programs.

18 (d) EFFECTIVE DATE.—The amendments made by
 19 subsections (a) and (b) take effect upon the expiration of
 20 the 60-day period beginning on the date of enactment of
 21 this Act, without regard to whether a final rule to imple-
 22 ment such amendments has been promulgated by the Sec-
 23 retary of Health and Human Services under section
 24 701(a) of the Federal Food, Drug, and Cosmetic Act (21
 25 U.S.C. 371(a)). The preceding sentence may not be con-

1 strued as affecting the authority of such Secretary to pro-
2 mulgate such a final rule.

3 **SEC. 3. REPORTS REGARDING INTERNET-RELATED VIOLA-**
4 **TIONS OF FEDERAL AND STATE LAWS ON DIS-**
5 **PENSING OF DRUGS.**

6 (a) IN GENERAL.—The Secretary of Health and
7 Human Services (referred to in this section as the “Sec-
8 retary”) shall, pursuant to the submission of an applica-
9 tion meeting the criteria of the Secretary, award a grant
10 or contract to the National Clearinghouse on Internet Pre-
11 scribing (operated by the Federation of State Medical
12 Boards) for the purpose of—

13 (1) identifying Internet sites that appear to be
14 in violation of Federal or State laws concerning the
15 dispensing of drugs;

16 (2) reporting such sites to State medical licens-
17 ing boards and State pharmacy licensing boards,
18 and to the Attorney General and the Secretary, for
19 further investigation; and

20 (3) submitting, for each fiscal year for which
21 the award under this subsection is made, a report to
22 the Secretary describing investigations undertaken
23 with respect to violations described in paragraph (1).

24 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
25 purpose of carrying out subsection (a), there is authorized

- 1 to be appropriated \$100,000 for each of the fiscal years
- 2 2004 through 2006.

